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Appeal Brief filed August 23, 2004

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August 23, 2004

Date

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Application No.** 09/925,063      **Group Art Unit:** 1615  
**Applicant(s):** Barnes, S. and Ding, J.      **Examiner:** JOYNES, ROBERT M.  
**Filing Date:** August 8, 2001      **Docket No.** 70373-010100  
**Title:** CALENDERED HYDROCOLLOID DRESSING      **Customer No.** 33717

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**APPELLANT'S BRIEF (37 C.F.R. § 1.192)**

This brief is in furtherance of the Notice of Appeal in this case, timely filed June 22, 2004. Applicant hereby appeals to the Board from the decision of the Primary Examiner in the Advisory Action mailed June 17, 2004 in response to Applicants' After Final Response filed on May 12, 2004, maintaining the final rejections in the Final Office Action mailed March 23, 2004 of all the then pending claims (21-66), including claims 21-28, 32-40, 42-52, 56-64 and 66. A Response and Amendment was filed after the Final Office Action mailed March 23, 2004, and accordingly, claims 21-23, 26-31, 34-43, 45-47, 49-55, 58-59 and 61-66 are now on Appeal. This Brief is accompanied by authorization to charge the requisite fee set forth in § 1.17(c) to Deposit Account 50-2638.

**(1) REAL PARTY IN INTEREST**

The real part in interest in this appeal is Scapa North America, the assignee.

(2) RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences that will directly effect or be directly effected by or have a bearing on the Board's decision in this appeal.

(3) STATUS OF CLAIMS

In the present application, sixty-six claims have been filed. Claims 1-20, 24-25, 32-33, 44, 48, 56-57 and 60 are canceled without prejudice or disclaimer. Claims on Appeal are set forth in Exhibit A of this brief and are: claims 21-23, 26-31, 34-43, 45-47, 49-55, 58-59 and 61-66. These include independent claims 21, 43, and 45. Claims 21, 43-45 were rejected based on 35 U.S.C. §112, second paragraph and claims 21-28, 32-40, 42-52 56-64 and 66 are rejected under 35 U.S.C. §103 (a) in the Final Office Action mailed March 23, 2004.

(4) STATUS OF AMENDMENTS

An Amendment and Response after Final Rejection was filed on May 12, 2004, the amendments and arguments therein being based upon suggestions made by Supervisory Patent Examiner Thurman K. Page during teleconference discussions held on May 4<sup>th</sup>, 2004 to discuss the Final Office Action mailed on March 23, 2004. According to the Advisory Action mailed June 17, 2004, these after final amendments have been entered for purposes of Appeal.

(5) SUMMARY OF INVENTION

In one aspect, the present invention is directed to providing an efficient method for manufacturing calendered hydrocolloid dressings. For example, a calendered hydrocolloid dressing manufactured by the method described in the present application has improved film strength, particularly when the dressing is saturated. Furthermore, a hydrocolloid dressing manufactured by the method described in the present application has improved dimensional stability. Finally, the process of manufacturing calendered hydrocolloid dressings is more efficient and economical relative to other prior art methods, at least because there are fewer stages of mixing and fewer components of manufacture required.

Preferably, the hydrocolloid dressing is manufactured using a calender process to form a backing film to which is applied an adhesive layer, to the backing film's lower surface.

Furthermore, the calender process used to manufacture the hydrocolloid of the present invention can be carried out in the absence of a release liner. However, after the manufacture of the hydrocolloid dressing, a release liner can be applied to the adhesive layer's lower surface area to facilitate conversion of the dressing, or to protect the adhesive before application of the dressing to a user, for example.

In one method of manufacturing the hydrocolloid dressing 11, a multi-roll calender process is used to form the backing film layer 15 and apply the adhesive layer 17 in a single manufacturing step (as shown in FIG. 3 of the pending application). The backing film composition 115 is formed by blending, for example, selected polymers, antioxidants, processing aids and/or stabilizers in selected proportions which are metered, mixed and extruded, via a single screw extruder 33, for example. The temperature of the backing film composition 115 when extruded is preferably in the range of about 350-400 degrees F., and most preferably about 380 degree. F. The backing film composition 115 is delivered to the multi-rolled calender 35 in a continuous fashion for forming into the backing film layer 15. The backing film layer thickness 25 is determined by the width of the top gap 37 between the calender top roll 39 and center roll 41 (please see page 8, paragraph 42).

The method of manufacturing for the adhesive composition can be achieved, but is not limited to the method or order of operations as described below. For example, adhesive composition ingredients including polyisobutylene (PIB) and Butyl rubber, may be added in a sigma blade mixer and heated to about 150 degree. C. under nitrogen blanket. The ingredients are preferably heated until they are completely melted, and additionally the Parapol then added. The mixture is preferably mixed until the composition is homogeneous. The temperature is preferably reduced to about 120 .degree. C. Hydrophilic particles may then be blended into the heated adhesive composition and mixing continued until the particles are mixed uniformly throughout. The mixture is then discharged from the mixer and ready for calendaring. The adhesive composition 117 is calendered onto the backing film layer 15 between the center roll 41 and lower roll 45 (please see page 9 paragraphs 44-46).

One of the novel aspects taught by the pending application entails a manufacturing process, particularly the simultaneous formation of an adhesive layer and lamination of the

formed/forming adhesive layer between a center roll and a lower roll to form a hydrocolloid dressing comprising a backing film layer and an adhesive layer in a single manufacturing step (please see Figure 3, pages 8- 9 and claim 21 in application as filed).

As defined in the claims, the method for manufacturing a calendered hydrocolloid dressing includes a one-step method whereby a layer of adhesive, such as a polymeric adhesive, is applied, formed and calendered directly onto a backing film layer to provide the hydrocolloid dressing. Additionally and for example, additional method steps include blending a backing film composition containing an ethylene-based copolymer, extruding the backing film composition, calendering the backing film composition between a first roll and a second roll to form a backing film layer, blending a polymeric pressure-sensitive adhesive composition containing hydrocolloids (see Figure 3). The method of manufacturing is defined by all of the pending independent claims such that the formation of the layer of polymeric adhesive, application of the polymeric adhesive and lamination of the layer of the formed polymeric adhesive to the firstly formed backing all occur in one step between two rolls (referenced as “a center and lower roll” in claim 21 or second and third roll in claims 43 and 45).

Applicants have identified and provided a single step of layer formation and lamination to the backing layer which results in a clear economic advantage for producing calendered hydrocolloid dressings, as opposed to prior art methods of forming the adhesive layer separately. For example, such layers are provided as pre-made films, typically at another manufacturing location. This and then laminating the film/layer onto a backing as a separate step. The claimed methods result in improved manufacturing efficiency and hence provide an economic advantage over prior art methods.

And what is disclosed by the prior art references cited by the Examiner? Nothing remotely recognizing or even mentioning any method steps, much less the unique and efficient method steps recited in the present claims are disclosed in any of the references. As discussed below, the principal references are:

a method for preparing adhesive dressings containing a pharmaceutically active ingredient (U.S. Patent No. 5,059,189, herein after *Cilento, et al.*)

a breathable flexible backing for a transdermal drug preparation with a water vapor transmission rate about equal to or in excess of that of ethylene vinyl alcohol copolymer (U.S. Patent No. 4,994,278, herein after *Sablotsky, et al.*) and

a transdermal drug delivery device (U.S. Patent No. 5,372,819, hereinafter *Godbey, et al.*).

Thus, whereas Applicants not only recognized a need for improved manufacturing efficiency but came up with a workable and efficient solution which is now set forth in the claims, the cited prior art did not even recognize this need, much less come up with the claimed solution to fill this need.

#### (6) ISSUES

Now, turning to the specific rejections the following rejections were included in the final rejection:

1. Claims 21 and 43-45 were rejected under 35 U.S.C. §112, second paragraph.
2. Claims 21-28, 32-40, 42-52, 56-64 and 66 are rejected are rejected under 35 U.S.C. §103 (a) as being unpatentable over *Cilento, et al.* in combination with *Sablotsky, et al.*.
3. Claims 29-31, 41, 53-55 and 65 are rejected under 35 U.S.C. §103 (a) as being unpatentable over *Cilento, et al.* in combination with *Sablotsky, et al.* in further combination with *Godbey, et al.*.

#### (7) GROUPING OF CLAIMS

All of the claims are considered individually patentable and should be considered separately and do not stand or fall together. In accordance with 37 CFR 1.192, Appellants presents reasons in the argument section of this Brief why each of these claims and claim sets are separately patentable.

#### (8) ARGUMENTS

For completeness, it is noted in passing that the file history includes the following papers.

A) BACKGROUND

The Patent Application was filed on August 8, 2001 and issued Serial No. 09/925,063. An Assignment was recorded on February 22, 2002.

The first Office Action was mailed October 10, 2002, rejecting all the claims (1-23).

An Information Disclosure Statement was filed on December 26, 2002.

A response to the first Office Action was filed January 13, 2003, adding claims 24-42.

A second, Final Office Action was mailed on April 4, 2003, again rejecting all the claims (1-42).

An Amendment adding a new claim (claim 43) in response to the Final Office Action and a Request for Continued Examination was filed June 30, 2003.

Another Office Action was mailed August 26, 2003, by the original Examiner, Robert M. Joynes, again rejecting all claims (1-43).

A response to the August 26, 2003 Office Action was filed December 24, 2003, adding claims 44-66 and canceling article claims 1-20.

A second Final Office Action was mailed March 23, 2004, again rejecting all pending claims (21-66).

An Amendment and Response After the Final Rejection of March 23, 2004 was filed May 12, 2004 in light of and according to amendments recommended by Supervisory Examiner Thurman K. Page during discussions held on May 4th, 2004. Claims 24-25, 32-33, 44, 56-57, 60 were cancelled, the subject matter being incorporated into the independent claims, as suggested by Supervisory Examiner Thurman K. Page.

An Advisory Action was mailed June 6, 2004, maintaining rejections of pending claims over the same prior art asserted in the Final Office Action mailed March 23, 2004.

A Notice of Appeal was filed on June 22, 2004.

The present Appeal Brief is filed on August 22, 2004.

B) REJECTION of Claim 21, 43 and 45 under 35 U.S.C. §112, second paragraph

The Examiner has rejected claim 21 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention. According to the Office Action of March 23, 2004 and Advisory Action of June 6, 2004, the Examiner seeks clarification as to how claim 21 differs from then pending claims 43-45. More particularly, the Examiner has stated that claim 21 and 43 appear to be duplicate claims.

Applicants respectfully point out that (as already pointed out in the Amendment and Response After the Final Rejection filed May 12, 2004) claim 21 recites a top, center and lower rolls while claim 43 recites first, second and third rolls. Such varying recitations/configurations emphasize that the method claimed may be practiced utilizing apparatus in a “top-down” sequence (please see Figure 3) as well as run in reverse, that is, from the “bottom-up”. While the exemplary “top down” sequence illustrated in Figure 3 depicts formation of a backing film layer between a top and center rolls, and adhesive layer deposition, formation and lamination to the backing film layer carried out in one step between the center and a bottom roll, the process can just as well be run in a “bottom up” configuration. Namely, that the backing film layer is formed between the bottom and center rolls, after which the one step adhesive layer deposition, formation and lamination to the backing film layer is carried out between the center and top rolls.

Claim 43 utilizes the terms “first roll, second roll and third roll”. These terms are also applicable to the process exemplified in Figure 3 and also do not limit the process to a configuration where a backing layer is first formed between a top and center roll, and where the one-step adhesive layer deposition, formation and lamination to the backing film layer is carried out at a center and bottom roll, as recited in claim 21. Instead, use of the terms “first roll, second roll and third roll” encompasses both of the “top down” and “bottom up” order of operations and roller labeling, without possibly perceived spatial relation limitations of the terms top, center and bottom recited in claim 21.

Applicants respectfully have to disagree with the Examiner's statement in the Advisory Action that this "... connotation is not readily apparent from the claims or the specification". One look at Figure 3 makes the Applicants' assertions plainly evident and clear, particularly to one of ordinary skill in the art. Such connotations are explicitly evident by the provided teachings of the present application, particularly Figure 3.

Applicants accordingly traverse the 35 U.S.C. §112, second paragraph rejection of claim 21.

The same arguments made with respect to claim 21 above also apply to claims 43 and 45. Claims 43 and 45 are independent claims that describe the invention and further distinguish the invention over the prior art and from each other.

It is noted in passing that claim 44 had been canceled in the Amendment and Response After the Final Rejection filed May 12, 2004 and is no longer pending, and thus the Examiner's 35 U.S.C. §112, second paragraph rejection of this claim is moot.

Applicants respectfully point out that claim 21 recites in step e. "...calendering the adhesive composition..." while claim 43 recites, in step e. "...calendering the polymeric pressure-sensitive adhesive composition". Thus, clearly claims 21 and 43 are difference at least in this respect, in addition to the recitations relating to top center and lower rolls of claim 21 and first, second and third rolls of claim 43, as discussed above. Applicants therefore respectfully traverse the 35 U.S.C. §112, second paragraph rejection of claim 43.

Furthermore, the Examiner has stated that "Claim 45 recites that the adhesive layer is formed and adhered to the backing layer in one single manufacturing step. Yet the claims recites (sic) that the blend is extruded and THEN calendered. This would appear to be at least two manufacturing steps, not one." (Office Action of March 23,2004).

Applicants respectfully point out that the Examiner has not appreciated the meaning of the single manufacturing step recited in claim 45, or in any of the independent method claims, wherein the polymeric pressure-sensitive adhesive composition is applied and calendered directly onto the backing film layer such that formation of the adhesive layer of the polymeric pressure-sensitive adhesive composition and lamination of the adhesive layer to the backing film



layer is achieved in a single manufacturing step, as plainly recited in the claim. The extrusion step has nothing to do with the object of the recited single manufacturing step. This one-step method is also clearly recited in independent claims 21 and 43 and has been pointed out to Examiners Joynes and Page during teleconferences. Additionally, claim 45 recites the blending of a thermoplastic elastomer that will comprise the backing film layer, as opposed to the ethylene-based copolymer of claim 43. Applicants respectfully traverse the 35 U.S.C. §112, second paragraph rejection of claim 45.

C) REJECTION of Claim 21 UNDER 35 U.S.C. 103(a)

The Examiner has rejected independent claim 21 under 35 U.S.C. 103(a) as being unpatentable over Cilento et al. in combination with Sablotsky et al., asserting that in light of certain reasoning set forth in the Office Action of March 23, 2004, it would have been obvious to combine the above references to arrive at the Applicants' pending method claims, even though independent claim 21, which includes nearly all of the elements shown in Figure 3 of the application, defines structure which is clearly not shown or taught in any way, shape or form by the cited references.

Applicants' point out the fact the Examiner, since the first Office Action mailed October 2, 2002, has consistently failed to show where in the cited references the claimed method steps are to be found. The Examiner repeatedly rejects the method claims of the application in light of composition teachings of Cilento et al. and Sablotsky et al., which are directed to and teach various compositions for adhesive dressings and backings, respectively. In fact, reasoning repeatedly cited by the Examiner to reject the pending method claims states that "...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d454, 105 USPQ 233, 235 (CCPA 1955) (on page 2 of Office Action mailed October 2, 2002, on page 3 of Office Action mailed April 9, 2003, on page 3 of Office Action mailed August 26, 2003 and finally on page 4 of the Final Office Action mailed March 23, 2004). Applicants' have, repeatedly as well, pointed out to the Examiner that such reasoning regarding ranges and concentrations have nothing to do with the recited method steps of the pending method claims. Applicants have also requested that the Examiner explicitly point out where in the cited references could one find

anything resembling the structure recited in the independent method claims, including claim 21. The Examiner, despite several Office Actions, fails to show, even once, where support for such rejections of method claims may be found in the cited references.

The Examiner has not provided any such evidence, other than generalized statements that "...at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use any known polymeric component(s) for the backing layer of a transdermal composition and to adjust the concentrations of the ingredient and to adjust the thickness of the individual layers. No criticality is seen in the particular monomeric ranges...no unexpected results are seen from the particular monomeric concentrations." (page 4, Final Office Action mailed March 23, 2004).

What does any of this reasoning have to do with the claimed method steps of independent claim 21? Absolutely nothing, and furthermore, the Examiner's proposed motivation for combining Cilento et al. and Soblotsky et al., "...to increase or decrease the barrier properties of the backing layer..." is not sound because there is nothing in either of the references that would suggest that the motivation for combining the references in such a way that results in the claimed invention, directed to method steps of manufacturing a hydrocolloid dressing. In fact, the Examiner states that "Neither Cilento nor Sablotsky teach the exact concentration ranges of the polymeric backing layer." (page 4 of Final Office Action mailed March 3, 2003). How is it that this stated reasoning applies to independent claim 21, where method steps such as calendering the adhesive composition between the center roll and a lower roll to form a hydrocolloid dressing comprising a backing film layer and an adhesive layer, wherein the polymeric pressure-sensitive adhesive composition is applied and calendered directly onto the backing film layer such that formation of an adhesive layer of said polymeric pressure-sensitive adhesive composition and lamination of said adhesive layer to said backing film layer is achieved in a single manufacturing step, are recited?

Furthermore, generic statements of what one of ordinary skill in the art would do in relation to concentration adjustments, thickness, use of "...any known polymeric component(s), backing layer characteristics, including color flexibility, etc..." as stated in the Final Office Action mailed March 3, 2004 as well as in other Office Actions, are precisely hindsight and are

not allowed, particularly when pending claim limitations and the teachings of the present invention are compared to the cited references. As stated in Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., "...Inventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system, possess something, which sets them apart from the workers of ordinary skill, and one should not go about determining obviousness under § 103 by inquiring into what patentees (i.e., inventors) would have known or would likely have done, faced with the revelation of references." Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 230 U.S.P.Q. 416 (Fed. Cir. 1986). Additionally, the Federal Circuit states and makes clear that, "the deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is "basic knowledge" or "common sense" to one of ordinary skill in the art." In re Zurko, 59 USPQ2d 1693 (Fed. Cir. Aug 2, 2001). There must be some showing or evidence provided by the Examiner, which is clearly lacking in the pending case.

The rejection is clearly improper and Applicants accordingly traverse the rejection of claim 21 based on these two references that fail to teach manufacturing method steps and for the following additional reasons:

The applicable law requires a teaching or suggestion to combine references to teach the invention.

Establishing a prima facie case of obviousness requires that three basic criteria be met. First, there must be a clear and particular suggestion or motivation, either in the prior art or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the references being relied on to reject the claimed invention. Second, the combination of references must teach or suggest all of the requirements or elements of the invention. Third, there must be a reasonable expectation of success.

In the Final Office Action, the Examiner's rejections under 35 U.S.C. 103(a) combine a prior art method for preparing an adhesive dressing (Cilento et al.) with a breathable backing construction (Sablotsky et al.). However, in the present case, there is no indication or suggestion as to why the prior art method for preparing an adhesive dressing of Cilento et al. might be combined with breathable backing construction of Sablotsky et al., particularly in order to

obviate the pending method claims. The proposed obviousness reasoning provided by the Examiner (as cited above page 4, Final Office Action mailed March 23, 2004) and motivation to combine the references "...to increase or decrease the barrier properties of the backing layer..." is not sound. What and how does such a combination render obvious the methods steps positively recited in independent claim 21, particularly and for example in regards to step e.?

On the other hand, applicant has created a new and useful large scale, fully controlled hydrocolloid dressing manufacturing system for use in large scale fabrication of these dressings. It is respectfully suggested that it is only through Applicants' teachings that the disparate references could be combined as suggested in the Office Action, and even then, such a combination does not even approach suggesting the Applicants' claimed methods. Essentially the Office Action has used applicant's specification as a road map to combining references, and this type of hindsight reconstruction of prior art references has been widely condemned.

With regard to the use of "hindsight", or the use of the applicant's teachings to combine prior art, the courts have universally condemned such specious combinations and have upheld the validity of patents or claims of patents in which such hindsight was employed to combine the references. Notable among the decisions relating to the subject matter is the decision of the Supreme Court of the United States in the case of Diamond Rubber Co. of New York v. Consolidated Rubber Tire Co., 220 U.S. 428, 31 S. Ct. 444 (1911). In this case the Supreme Court stated "Many things, and the patent law abounds in illustrations, seem obvious after they have been done, and 'in the light of the accomplished result,' it is often a matter of wonder how they so long 'eluded the search of the discoverer and set at defiance the speculations of inventive genius'. . . . Knowledge after the event is always easy, and problems once solved present no difficulties, indeed may be represented as never having had any . . ." Id. at 434-35, 31 S. Ct. at 447 (citation omitted). The Supreme Court then went on to uphold the patent under consideration.

In a similar vein, the Court of Customs and Patent Appeals stated in the case of In re Kamm and Young, 172 U.S.P.Q. 298 (C.C.P.A. 1972), that the basic mandate inherent in 35 U.S.C. § 103 is that piecemeal reconstruction of prior art patents in the light of applicant's disclosure shall not be basis for holding of obviousness. Similarly, in the case of Ex Parte

Lange, 72 U.S.P.Q. 90, 91 (C.C.P.A. 1947), the Court said, “It seems to use that the Examiner is using appellant’s disclosure for the suggestion of the combination since there is no suggestion in any of the patents for their combination in the manner claimed by applicant. The cases of Ex Parte Myerson, 72 U.S.P.Q. 49 (C.C.P.A. 1946), and Ex Parte Gary, 76 U.S.P.Q. 224 (C.C.P.A. 1947), are to the same effect. Two other cases decided by the C.C.P.A. in which hindsight was condemned are In re Stephens, Wenzel, and Browne, 145 U.S.P.Q. 656 (C.C.P.A. 1965), and In re Leonor, 158 U.S.P.Q. 20 (C.C.P.A. 1968). In the Stephens case, the Court stated that “References may not be combined indiscriminately and with guidance from applicant’s disclosure to show that claims are unpatentable.” 145 U.S.P.Q. at 657. In the Leonor case, the court dismissed the examiner’s rejection of the claims in suit as “hindsight reconstruction of prior art” and disapproved of the board’s affirmance of that rejection on the basis that it “violates [the] intent and spirit of 35 U.S.C. § 103.” 20 U.S.P.Q. at 20-21. In Leonor, the court said that the issue is “whether teachings of prior art would of themselves, and without benefit of applicant’s disclosure, suggest [a process] which would make claimed invention obvious...” (emphasis court’s). Id. at 21.

The Court of Appeals for the Federal Circuit has been equally strong in its condemnation of “hindsight” or similar rejections. Thus, for example, in ACS Hospital Sysesm, Inc. v. Montefiore Hospital, 221 U.S.P.Q. 929 (Fed. Cir. 1984), the Federal Circuit reversed a holding of invalidity because there was no teaching to combine the references. Similarly, the Federal Circuit, in W.L. Gore Associates, Inc. v. Garlock, Inc., 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983), referenced the “insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher, “ and condemned this type of rejection or holding of unpatentability.

The rejection is clearly improper, based at least upon hindsight, as the proposed motivation to combine Cilento et al. and Sablotsky et al. is not directed to the claim differences, that is, elements of the claims. The pending elements of claim 21 are completely unrelated to even the Examiner’s asserted teachings of the cited art. Such 35 U.S.C. 103(a) rejections are improper and must be withdrawn.

As more fully described in the attached Declaration of Scott Barnes, the present invention provides a need in the art for a more efficient and cost effective method for providing hydrocolloid dressings. The Declaration points out that in the past, manufacturing methods considered by persons skilled in the art to utilized additional and costly manufacturing steps to provide the various layers that would eventually be combined to form various dressings. Indeed, such exemplary prior art methods are provided and evidenced by the disclosure of Cilento et al., where the adhesive is coated onto a separate layer (release coated layer) to form a first construction, this construction is then laminated in another step to another backing layer. The pending method claims, including claim 21, recite a one step method whereby the adhesive layer is applied, formed and laminated directly onto a backing film layer in one step (see Figure 3 in pending application).

The Declaration additionally points out that it is the inventor's opinion that the references which have been cited by the Examiner do not belong or relate to the claimed method claims pending in the instant case.

Furthermore, the cited combination of references clearly fails to teach or suggest all of the requirements or elements of the claimed invention. Additionally, there is no showing by the Examiner of a reasonable expectation of success, as the combination of Cilento et al. and Sablotsky et al. do not even mention the method elements claimed in claim 21, so what showing of success of a non-taught or disclosed method could there be?? Clearly the Examiner fails to even make a prima facie showing of obviousness.

One "objective indicia of patentability" involves whether the prior art recognized a problem that is overcome by the present invention. In the present case it is clear that the prior art references provide no indication of a problem faced by the inventors, i.e., improving the efficiency of hydrocolloid dressing manufacturing by condensing separate manufacturing steps into one efficient step.

Regarding the legal issue of recognition of the problem, it is submitted that 35 U.S.C. § 103 requires that the subject matter "as a whole" must be obvious in order for an invention to be found unpatentable. Of course, recognition of the problem is part of the inventor subject matter

as a whole, and where the recognition of the problem was not present in the cited art, and where the claims define the entire invention, patentability is clearly present.

Where there is no overall recognition of the problem, the rejection necessarily used Applicants' specification as a road map to reconstruct the claimed invention. One very pertinent supporting decision is the U.S. Supreme Court case of Eibel Process Co. v. Minnesota and Ontario Paper Co., 261 U.S. 45 (1923), in which the U.S. Supreme Court stated "it was discovery of the source (of trouble) not before known and the application of the remedy for which Eibel was entitled to be rewarded in his patent". Similarly, in the present case, where the inventors were the first to conceive the overall problem (separate unnecessary steps for forming an adhesive layer and subsequently applying and laminating the previously formed adhesive onto a backing layer) and the resultant solution (forming and laminating the adhesive layer to a backing film layer in one step), they should definitely be awarded a patent. Early decisions of the Court of Customs and Patent Appeals, the forerunner of the Court of Appeals for the Federal Circuit, are to the same effect. In the case of In re Worrest, 96 U.S.P.Q. 381 (C.C.P.A. 1953), the court stated "discovery of problem and concept of new improvement for solving it must also be considered along with the actual physical means of achieving solution". Similarly, in the case of In re Osplack, 93 U.S.P.Q. 306 (C.C.P.A. 1952) the court stated "conception of doing a thing, result of which is new and useful, must be considered along with the actual steps of doing in considering presence of patentability." Even after combining the Cilento et al and Sablotsky et al. patents, there is no disclosure that even suggests the claimed manufacturing method steps, apparatus or compositions utilized in the conjunction with same.

Accordingly where none of the many cited references even disclose the problem, much less applicants' solution, there can be no valid finding of obviousness. Claim 21 is clearly allowable.

D) REJECTIONS of Claims 22-28, 34-40, 42-52, 58-64 and 66 UNDER 35 U.S.C. 103(a)

The Examiner has rejected Claims 22-28, 34-40, 42-52, 58-64 and 66 under 35 U.S.C. 103(a) as being unpatentable over the same combination of Cilento et al. and Sablotsky et al., asserting that in light of certain reasoning set forth in the Office Action of March 23, 2004, it

would have been obvious to combine the above references to arrive at the Applicants' pending method claims. Applicants' same arguments made with respect to independent claim 21 above also apply to dependent claims 22-28, 34-40, 42 which are directly or indirectly dependent therefrom. Method claim 43 is stand alone independent claim having no claims dependent therefrom. Method claim 45 is another independent claim from which dependent claims 46-52, 58-64 and 66 depend directly or indirectly therefrom.

Dependent claim 22 recites an additional manufacturing step of adhering a release liner to the dressing provided by the novel method steps recited in claim 21, as discussed above. Since neither of the cited references, alone or in combination, teach or suggest such method steps and dependant claim 22, which incorporates all of the limitations recited in claim 21, is clearly allowable.

Dependent claim 23 depends from dependant claim 22 and independent claim 21. Claim 23 is directed to hydrocolloid dressings prepared by the novel and nonobvious manufacturing steps clearly recited in claim 21 (without adhering a release liner to the dressing) and dependent claim 22 (incorporating this adhering step and liner). As such and discussed above, such hydrocolloid dressings provided by Applicants' claimed novel and efficient manufacturing methods are nowhere to be found in the cited Cilento et al. and Sablotsky et al. references. Therefore, dependant claim 23 is allowable in light of the cited art.

Claim 26 is a dependent claim which depends from claim 21 and further points out and distinguishes particular aspects of the present invention, particularly over the two cited references. Claim 26 positively recites that the ethylene based copolymer utilized for the backing film composition is one or a combination of any of an ethylene acrylic acrylate, ethylene butyl acrylate, ethylene ethyl acrylate or ethylene methyl acrylate copolymer. As stated by the Examiner in the Office Action mailed March 3, 2003, the primary reference, Cilento et al. does not teach that the backing layer comprises ethylene acrylic acrylate or ethylene butyl acrylate or ethylene methyl acrylate or the specific monomer concentrations (of claim 1 which was cancelled at that time).

In addition to noting that it appears that this type of rejection asserted by the Examiner relates to a cancelled claim, Applicants also note that claim 26 incorporates all of the limitations



of independent claim 21. Furthermore, the secondary Sablotsky et al. reference clearly fails not only to teach what the Examiner has admitted, but fails to remedy the lack of teachings regarding the manufacturing steps relevant to the claimed method steps of subsumed claim 21 and backing film composition component limitations of claim 26. This is also an improper rejection, as the Examiner's proposed motivation to combine the references (increase or decrease barrier properties of the backing layer) is contrary to the stated purpose of the reference (Cilento et al. for particulars regarding thickness and components of the dressing and Sablotsky et al. for teaching ethylene methyl acrylate). There is nothing in either of the references that would suggest motivation to combine the references to arrive to the currently pending claimed method steps that are part of claim 26. Therefore, dependant claim 26 is allowable in light of the cited art.

Claim 27 is a dependent claim of claim 21, which recites particular component concentrations that make up an exemplary backing film layer made in accordance with the teachings of the present disclosure. Obviously, the arguments presented above regarding the method steps positively recited in subsumed claim 21 are also applicable here. Accordingly, and since no such method step recitations may be found in the cited references, dependent claim 27 is also allowable.

As discussed in arguments above regarding claim 21 and 27, claim 28 also further distinguishes the claimed method steps from any explicit or implicit teachings found in both Cilento et al and in Sablotsky et al., alone or in combination. Claim 28 is also dependant from claim 21 and is therefore also allowable for the same reasons presented above, at least by the fact that no teachings or disclosure of method steps, such as a one step manufacturing method by which an adhesive layer of a composition is formed and laminated to a provided backing film layer, is to be found in either cited reference. Therefore, dependant 28 is also an allowable claim.

Claim 34 is also a dependant claim that depends from independent method claim 21. Claim 34 adds a further limitation to the polymeric pressure sensitive adhesive composition recited in claim 21 by namely further requiring that the composition contain at least one rubber. Since the claim incorporated the limitations of the method steps recited in claim 21, which are

simply not found or taught in the cited references, even if combined, claim 34 is an allowable claim.

Claim 35 is a dependent claim that further limits the rubber recitation of claim 34, by positively reciting that the rubber is any one of or a combination of any one of styrene-isoprene-styrene copolymers, styrene-ethylene-styrene copolymers, styrene-butylene-styrene copolymers, butyl rubber and polyisobutylene. These recitations, when combined with the limitations of claim 34 and 21, render claim 35 clearly patentable over Cilento et al. and Sablotsky et al., alone or in combination, since method steps recited in claim 21 (from which claim 35 indirectly depends) are not to be found in these references, as previously pointed out. Claim 35 is thus resultantly allowable.

Claim 36 is another dependent claim that depends from claim 21. Claim 36 further distinguishes the invention from the cited prior art, by reciting the additional limitation of an additive to the adhesive layer formed by the novel method steps recited in claim 21. Once again, since no teaching or disclosure may be found in the cited references (combined or alone) that relate to the claimed limitations positively recited in independent claim 21 and dependent claim 36 (as discussed in detail in the discussions regarding claim 21 and the cited references), claim 36 is allow able.

Similarly, claim 37, which depends from claim 36 and further differentiates a particular aspect of the currently pending method claims from the cited composition art, is also allowable. Claim 37 further defines the additive limitation of claim 36 as any one or a combination of any of tackifiers, stabilizers, plastifiers, processing aids or therapeutic agents. It is further noted that the arguments set forth hereinabove relative to claim 21 are also largely applicable to claim 37, and are hereby incorporated by reference relative to claim 37. Since the cited references do not teach the method steps that are part of claim 37, claim 37 is an allowable claim.

Claim 38 is a dependant claim that depends directly from method claim 21. Claim 38 further defines particular ranges of components of polymer, hydrocolloid and additives that comprise the adhesive layer that is recited and formed in method claim 21. As discussed above, the method steps that are incorporated and are part of the limitations of dependent claim are not found in the cited and combined references, particularly a composition made up of the particular

amounts recited in claim 38, which are utilized and subjected to the novel manufacturing steps recited in claim 21. Accordingly claim 38 is allowable.

The arguments relating to claim 38 also apply to claim 39, which recites specific particulars regarding amounts of various components of the adhesive, which further distinguishes this claim from the cited prior art combination. As claim 38 is allowable, so is dependent claim 39, as claim 39 is dependent from claim 21.

Claim 40 is a dependent claim that depends from claim 21. Claim 40 positively recites and further limits the color of the adhesive layer, the backing film layer or both to being substantially transparent or clear. This further distinguishes the resultant hydrocolloid dressing provided by the method claimed in claim 21. As the combined references fail to disclose or suggest such manufacturing steps, particularly such steps in conjunction with adhesives and/or backing layers that are substantially transparent or clear, claim 40 is allowable.

Claim 42 is another claim dependant from claim 21, which recites particular thickness of the adhesive layer and the backing film layer. The particular ranges of thickness are not taught in the cited references and, as above, no manufacturing steps are found in the references that are even remotely approach the limitations of the steps recited in claim 21. Furthermore, any ranges or components that are disclosed in the cited references are not in conjunction with the method step limitations recited in claim 21. Accordingly, claim 42 is allowable.

Claim 43 is an independent claim, and the points, authorities and arguments discussed and relating to independent claim 21 are also applicable to independent claim 43 and are herein incorporated by reference. Claim 43 details a method for manufacturing calendered hydrocolloid dressings comprising various steps, particularly including a one step method for applying, forming and laminating an adhesive layer of polymeric pressure sensitive adhesive to a backing film layer between a second and third roll. As stated above and as detailed in the arguments relating to claim 21, the cited Cilento et al. and Sablotsky et al. references fail, alone or in combination, to disclose or even imply such a method step, as well as the structure recited in this claim. This claim simply cannot be read onto the cited references, in combination or otherwise. Accordingly, independent method claim 43 is clearly allowable in light of the prior art cited by the Examiner since the first of his four Office Actions.

Claim 45 is the third and final independent claim that is on Appeal. Similar to independent claims 21 and 43, claim 45 recites method steps for manufacturing a calendered hydrocolloid dressing. Claim 45 further differentiates the invention from the prior art and the other claims by positively reciting an extrusion step that disposes the polymeric pressure-sensitive adhesive composition onto the calendering apparatus recited, particularly onto a formed backing film layer. The polymeric pressure-sensitive adhesive composition is extruded, applied and calendered directly onto this backing film layer such that formation, calendering and lamination of the adhesive layer of polymeric pressure sensitive adhesive directly onto a backing film layer, between a second and third roll, occurs in one step, as enumerated above and shown in Figure 3.. As in the case for claim 21 and 43, such a combination of apparatus structure, compositions and method steps, as specifically and clearly recited in claim 45, is not found in the cited art, indeed not even pointed out by the Examiner. Accordingly and necessarily, independent claim 45 is also allowable.

The arguments presented that relate to dependent claim 22 are also applicable to dependent claim 46, which adds a step of adhering a release liner layer to the calendered hydrocolloid dressing provided in accordance with independent claim 45. Since no limitations or teaching are found in the cited references that meet the limitations of claim 46 (and subsumed claim 45), this claim is also allowable.

Multiple dependent claim 47 depends from dependant claim 46 and independent claim 45. Claim 47 is directed to hydrocolloid dressings prepared by the novel and nonobvious manufacturing steps clearly recited in claim 45 (without adhering a release liner to the dressing) and dependent claim 47 (incorporating this adhering step). As such and discussed above, hydrocolloid dressings provided by Applicants' claimed novel and efficient manufacturing methods are nowhere to be found in the cited Cilento et al. and Sablotsky et al. references. Therefore, dependant claim 47 is allowable in light of the cited art.

Dependent claim 49 depends directly from independent claim 45, further defining and distinguishing the thermoplastic elastomeric backing film composition recited and utilized in the method steps enumerated in claim 45. Claim 49 adds the limitation that the thermoplastic elastomeric backing film composition is an ethylene based copolymer. No such limitations,

including the steps recited in incorporated claim 45 and composition particulars recited in claim 49, are found in the cited art, alone or in combination. Claim 49 is allowable.

The same arguments and points proffered for claim 26 are also applicable to dependent claim 50. Claim 50 depends from dependant claim 49 and further points out and distinguishes particular aspects of the present invention, particularly over the two cited references. Claim 50 positively recites that the ethylene based copolymer utilized for the backing film composition is one or a combination of any of an ethylene acrylic acrylate, ethylene butyl acrylate, ethylene ethyl acrylate or ethylene methyl acrylate copolymer. As stated by the Examiner in the Office Action mailed March 3 , 2003, the primary reference, Cilento et al. does not teach that the backing layer comprises ethylene acrylic acrylate or ethylene butyl acrylate or ethylene methyl acrylate or the specific monomer concentrations (of claim 1, now cancelled). As above Applicants' note that it appears that this rejection asserted by the Examiner relates to a now cancelled claim. Applicants also note that claim 50 incorporates all of the limitations of independent claim 45. Furthermore, the secondary Sablotsky et al. reference clearly fails not only to teach what the Examiner has admitted, but fails to remedy the lack of teachings regarding manufacturing steps and structure relevant to the claimed method steps of subsumed claim 45 and backing film composition component limitations of claim 50. This is also an improper rejection, as the Examiner's proposed motivation to combine the references (increase or decrease barrier properties of the backing layer, Cilento et al. for particulars regarding thickness and components of the dressing and Sablotsky et al. for teaching ethylene methyl acrylate) has nothing to do with the method claims under examination. There is nothing in either of the references that would suggest motivation to combine the references to arrive to the currently pending claimed method steps that are incorporated and part of claim 50. Therefore, dependant claim 50 is allowable in light of the cited art.

Claim 51 depends from claim 45. Similar to dependent claim 27, claim 51 recites particular component concentrations that make up an exemplary backing film layer made in accordance with the teachings of the present disclosure. Obviously, the arguments presented above regarding the method steps positively recited in subsumed claim 45 are also applicable here. There are no details provided by the cited references, alone or in combination, regarding

the incorporated method steps or limitations of the subject matter of claim 51 and subsumed claim 45 . Accordingly, dependent claim 51 is allowable.

Claim 52 is similar to claim 51, in that a further limitation is recited, directed to the composition of the backing film layer that is utilized in the novel method step of independent claim 45, from which claim 52 depends. Here, the backing film layer includes a low density polyethylene homopolymer. As above, no method steps are found in the Cilento et al. and Sablotsky et al. references that relate to the claimed method of providing a hydrocolloid dressing, particularly where the backing film layer incorporates a low density polyethylene homopolymer. Since the limitations of claim 52 and incorporated claim 45 are not found in or taught by the cited references, claim 52 is allowable.

Claim 58 is also a dependant claim depending from independent method claim 45. Claim 58 adds a further limitation to the polymeric pressure sensitive adhesive composition recited in claim 45 by namely further requiring that the composition contain at least one rubber. Since this claim incorporates the limitations of the method steps recited in claim 45, which are simply not found or taught in the cited references, even if combined, claim 58 is another allowable claim.

Claim 59 is a dependent claim that further limits the rubber recitation of claim 58, by positively reciting that the rubber is any one of or a combination of any one of styrene-isoprene-styrene copolymers, styrene-ethylene-styrene copolymers, styrene-butylene-styrene copolymers, butyl rubber and polyisobutylene. These recitations, when combined with the limitations of claim 58 and 45, render claim 59 clearly patentable over Cilento et al. and Sablotsky et al., alone or in combination, since method steps recited in claim 45 (from which claim 59 indirectly depends) are not to be found in these references, as previously pointed out. Claim 59 is thus resultantly allowable.

Claim 61 depends from method claim 45 and further differentiates and specifies particular components of the adhesive layer provided by the method steps of claim 45. More particularly, claim 61 recites that the adhesive layer includes at least one additive, wherein the additive is any one or a combination of tackifiers, stabilizers, plastifiers, processing aids or therapeutic agents. No reference discloses the particulars of such an adhesive layer in

combination or utilized with the unique method steps outlines in claim 45. Accordingly and in light of the arguments presented for independent claim 45, claim 61 is allowable.

Dependent claim 62 recited particular percent ranges of polymer, hydrocolloid and additives, which details an adhesive composition that is useful for providing an adhesive layer which is made, formed and utilized as part of a resultant hydrocolloid dressing, in accordance with the method steps of claim 45. As stated above, there are no method steps or structure disclosed or suggested in the cited art that relates to the pending method claims, particularly in combination with particular formulations for the adhesive compositions useful therewith. Accordingly, claim 62 is allowable.

Claim 63 also depends from method claim 45, and recites particular percentages for polyisobutylene, butyl rubber, plasticizer and hydrocolloid that would comprise the adhesive layer of method claim 45. Once again, these particular limitations, in combination with the structural and method step limitations of claim 45 render this claimed method claim novel and unobvious over Cilento et al. in combination with Sablotsky et al., as both lack any applicable teachings or disclosure regarding the combined structural, method and composition limitations of claim 63, as well as any of the other pending claims. Therefore, claim 63 is another allowable claim.

Claim 64 is a dependent claim that depends from claim 45. Similar to claim 40, claim 64 positively recites and further limits the color of the adhesive layer, the backing film layer or both to being substantially transparent or clear. This further distinguishes the resultant hydrocolloid dressing provided by the method claimed in claim 45. As the combined references fail to disclose or suggest such manufacturing steps, particularly such steps in conjunction with adhesives and/or backing layers that are substantially transparent or clear, claim 64 is allowable.

Claim 66 is another dependent claim that further differentiates the present invention over the prior art, by reciting particular adhesive and backing film layers that can be obtained utilizing the novel method steps, including the one step forming and lamination step of step e. of method claim 45, from which claim 66 depends. As iterated previously, at least the method step limitations of parent claim 45 are not to be found in the references, alone or combined. The

combination of the limitation of claim 66 plus the limitations of claim 66 render claim 66 allowable.

E) REJECTIONS of Dependent Claims 29-31, 41, 53-55 and 65 UNDER 35 U.S.C. 103(a)

The Examiner rejected claims 29-31, 41, 53-55 and 65 under 35 U.S.C. 103(a) as being unpatentable over the same ill-fitting combination of references used above in the rejection of claim 21; as being unpatentable over Cilento et al. in combination with Sablotsky et al. and in further view of Godbey et al. (a "Transdermal Drug Delivery Device") to arrive at Applicants' claimed manufacturing methods. All of these rejections are traversed, arguments being presented individually below.

Claim 29 adds the limitation of further additives to the ethylene based copolymer that comprises the backing film composition of claim 21, from which claim 29 depends. The points, authorities and arguments discussed regarding claim 21 are also applicable to claim 29 and are incorporated here by reference. No reference or combination of references cited, including the additional Godbey et al. reference, discloses the full method steps or apparatus structure, here involving top, center and bottom rolls, and a one step method for forming and laminating an adhesive layer of polymeric pressure sensitive adhesive composition onto a backing film. Thus, even after combining these three references, the Patent Office rejection still lacks Applicants' claimed construction and limitations. For the intended application of applicant's manufacturing method, Applicants' arrangements provides improved and efficient methods for forming the desired hydrocolloid dressings, methods which are clearly lacking from the prior art even following the proposed combination of disparate references. The additional consideration of Godbey et al. fails to remedy this basic lack of finding of support in the cited references for the proposed rejections. Accordingly claim 29 is clearly patentable over the prior art. With regard to the assertion of unpatentability of this method claim, without any supporting reference, in the context of the other claimed elements of this claim, reference is made to In re Zurco, cited above. It is further noted that the arguments set forth hereinabove relative to claim 21 are also largely applicable to claim 29, and are hereby incorporated by reference relative to claim 29. Therefore claim 29 is allowable.



Claim 30 depends from claim 29, further distinguishing the additives recited in claim 29, more particularly relating to antioxidants, stabilizers and processing aids. Again, the method limitations of claim 21 are incorporated into claim 30. The addition of Godbey et al. to Cilento et al. and Sablotsky et al. does not remedy the deficiencies of these latter to references when it comes to disclosing the structural and method steps that clearly recited in this pending claim. The recitation of antioxidants, stabilizers and processing aids as part of the additives of the adhesive composition just goes to further differentiate and delineate the present invention over the three prior art references, even when combined. Accordingly, claim 30 is allowable.

Dependent claim 31 depends from claim 21, further defining the backing film layer as being comprised of about 65% to about 100% by weight ethylene methyl acrylate copolymer, from about 0 to about 35% by weight low density polyethylene, about 0.05 to about 2% by weight of any one of or combinations of any of antioxidants, processing aids or stabilizers. As detailed in the arguments of claim 30, the combination of the three references fails to disclose the limitations enumerated in claim 31. This includes, in addition to the ranges of the components recited in claim 31, the method steps and structure recited in parent claim 21. While we recite particular amounts/ranges, these limitations are not the only limitations of the claim that must be considered when determining patentability, but rather all of the limitations of this claim and the claim from which it depends must be considered. As stated repeatedly, none of the cited art alone or in any combination, including the additional Godbey et al. reference, recites the limitations of any of the pending independent claims, let alone the particulars of claims dependent therefrom. Therefore, claim 31 is allowable.

Claim 41, which depends from claim 21, further distinguishes the present invention over the prior art by reciting the limitation of providing a substantially flesh colored backing film layer, adhesive or both. As stated with regards to claim 21, the limitations of claim 21 must also be considered when determining the patentability of claim 41. For example, since the combination of structure (the various rollers), compositions (ethylene based copolymer and polymeric pressure sensitive adhesive composition) and method steps (such as the one step method for forming and laminating the polymeric pressure sensitive adhesive composition on the backing layer in step "e.") and color of the adhesive and/or the backing layer (substantially flesh

colored) is clearly not found or suggested in any combination of three cited references, this claim is also allowable.

Claim 53 adds the limitation of additives to the thermoplastic elastomeric backing film composition of claim 45, from which claim 53 depends. No reference or combination of references cited, including the additional Godbey et al. reference, discloses the full method steps or apparatus structure, here involving first, second and third rolls, and a one step method for forming and laminating an adhesive layer of polymeric pressure sensitive adhesive composition onto a thermoplastic elastomeric backing film composition. Thus, even after combining these three references, the Patent Office rejection still lacks this claimed construction and limitations. For the intended application of applicant's manufacturing method, Applicants' arrangements provides improved and efficient methods for forming the desired hydrocolloid dressings, which are clearly lacking from the prior art, even following the proposed combination of disparate references. The additional consideration of Godbey et al. fails to remedy this basic lack of finding support in the cited references for the proposed rejections. Accordingly claim 53 is clearly patentable over the prior art. With regard to the assertion of unpatentability of this method claim without any supporting reference, in the context of the other claimed elements of this claim, reference is made to In re Zurco, as cited herein.

Claim 54 depends from claim 53, further distinguishing the additives recited in claim 54, more particularly defining them as selected from the group consisting of antioxidants, stabilizers and processing aids. Again, the method limitations of claim 45 are incorporated into claim 54. The addition of Godbey et al. to Cilento et al. and Sablotsky et al. does not remedy the deficiencies of these latter two references when it comes to disclosing the structural and method steps that are clearly recited in this pending claim. The recitation of antioxidants, stabilizers and processing aids as part of the additives of the adhesive composition, goes to further differentiate and delineate the present invention over the three prior art references. Accordingly, claim 54 is allowable.

Claim 55 depends from claim 45, further defining the thermoplastic elastomeric backing film layer as being comprised of about 65% to about 100% by weight ethylene methyl acrylate copolymer, from about 0 to about 35% by weight low density polyethylene, about 0.05 to about

2% by weight of any one of or combinations of any of antioxidants, processing aids or stabilizers. As detailed in the arguments of claim 45, the combination of the three references fails to disclose the combination of structural, composition and method step limitations enumerated in claim 45. That is, the additional limitation of the ranges of the components recited in claim 55 in addition to the method steps and structure recited in parent claim 45. While we recite particular amounts/ranges, these limitations are not the only limitations of the claim that must be considered when determining patentability, but rather all of the limitations of this claim and the claim from which it depends must be considered and then found or taught in the cited prior art in order to render a proper rejection of this claim. The Examiner has simply not done so here.

As stated repeatedly, none of the cited art, including the additional Godbey et al. reference, recites the limitations of any of the pending independent claims, let alone in combination with the particulars of claims dependent therefrom, such as those recited claim 55. Therefore, claim 55 is allowable.

Dependent claim 65 depends from claim 45 and adds a limitation to claim 45, further distinguishing the present invention over the prior art by reciting the limitation of providing a substantially flesh colored backing film layer, adhesive or both. As stated in arguments above, the limitations of claim 45 must also be considered when determining the patentability of claim 65. For example, since the combination of structure (first second and third rollers), compositions (thermoplastic elastomeric backing film composition and polymeric pressure sensitive adhesive composition) and method steps (such as the one step method for forming and laminating the polymeric pressure sensitive adhesive composition on the backing layer in step "e.") and color of the adhesive and/or the backing layer (substantially flesh colored) is clearly not found in any of the three cited references, even when combined. Therefore claim 65 is allowable.

With regard to the "broad-brush" statements regarding motivations or certain matters being "well known in the art" or obvious, applicants respectfully traverse all such reasons for rejections, which essentially are asserting facts with no prior art support. In fact, Applicants have chosen components, method steps and compositions which suit the overall design of the Applicants' apparatus that is utilized in executing the novel and claimed manufacturing methods.

With regard to such unsupported assertions, they have been condemned in a recent decision of the Court of Appeals for the Federal Circuit in the case of In re Zurko, (Fed. Cir. No. 96-1258; 8/2/01). In this case the Court stated: "With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience – or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings." It is further noted that these broad-brush assertions in the rejection are in lieu of citing further references, which would make a rejection of the pending claim based on a further combination of these multiple references even less valid or compelling.

(9) CONCLUSION

The Examiner has failed to show in the cited prior art where one may find support for rejections of the pending claims on Appeal. There is simply no disclosure/support pointed out by the Examiner that is even relevant or reminiscent of the method steps positively recited in independent method claims 21, 43 or 45, or to claims dependent therefrom. All of the pending 35 U.S.C. 103 (a) rejections and the 35 U.S.C. 112, second paragraph rejections are traversed and are overcome, in light of the arguments, points and authorities present above.

Where Applicant's method claims are directed to new and efficient manufacturing steps for providing hydrocolloid dressings, the cited references may be considered composition disclosures, and do not disclose any teachings related to the method claims on Appeal.

In conclusion, the statement from the attached Declaration is significant. In this Declaration, under the penalty of perjury, one of the inventor states: "After analyzing the disclosures of all three of these cited references, I assert that there is no teaching or suggestion found in any of these references, alone or in combination, that meets the particulars of the independent method claims that are currently pending. In fact, there are no relevant method steps or manufacturing methods disclosed in the various cited references that relate to pending method claims steps."

It is noted that the Examiner in the case has failed to clearly point out, for the record, where in the cited references support may be found for rejecting the method claims of the instant application.

Furthermore, the claimed invention clearly constitutes "Progress in the Useful Arts" to use the Constitutional Phase (Art. 1, Sec. 8, Clause 8), and eminently deserves patent protection.

The allowance of all claims on Appeal in this Appeal is therefore respectfully solicited.


It is believed that this Appeal Brief has been timely filed. However, if mistaken the Commissioner is hereby authorized to charge any required fee in connection with the submission of this paper, now or in the future, or credit any overpayment to Account No. 50-2638. Please ensure that the Attorney Docket Number is referred to when charging any payments or credits for this case.

Respectfully submitted,

GREENBERG TRAURIG, LLP

Date August 23, 2004

By

  
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Attached:

Exhibit A: Claims on Appeal  
Exhibit B: Declaration of Scott Barnes